MAR 16 2000

K994287

Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

December 9, 1999

510(k) Summary

Submitter Information:

Company FONAR Corporation
Registration Number 2432211
110 Marcus Drive, Melville, New York 11747-4292

Contact: Luciano Bonanni Executive Vice President
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Device Designation:

Device Name: FONAR 360° Magnetic Resonance Imaging Scanner
Common Name: Magnetic Resonance Imaging Scanner (MRI Scanner)
Classification: System, Nuclear Magnetic Resonance Imaging (NMR/MRI)
Product Code: LNH (formerly 90JAM) Class: 2 Tier: 2
C.F.R. Section 892.1000 Classification Panel: Radiology

Applicable Performance Standards

On April 9, 1999, Intertek Services Corporation certified the Fonar Quality Management System to the standards EN ISO9001, BS EN9001 and ANSI/ASQC Q9001-1994. On May 25, 1999, the Fonar Quad 12000 was awarded the CE certificate and the quality system was certified to the additional standard of EN46001:1997. Our manufacturing systems were tested against the standards IEC 60601-1 (1988), IEC 60601-1-1 (1992-06), IEC 60601-1-2 (1993-04), IEC 60601-2-32 (1994-03) and IEC 60601-2-33 (1995-07). As part of the design/testing process for new products, Fonar utilizes the NEMA standards MS-1 through MS-8 for measuring performance and safety parameters (the standard MS-6 is not applicable to this submission). Images exported from the system utilize the DICOM standard.

Predicate Devices:

The magnet used in the FONAR 360° system is substantially equivalent to the magnet in use with the Fonar B3000 (P830076) and Quad 12000 (K951681) magnetic resonance imaging scanners. These magnets were selected as the predicate devices because of their similarities in intended use, magnetic field orientation, construction methods, materials and operating characteristics. They remain substantially equivalent to their previously approved forms.

Description of Device

The FONAR 360° magnet follows the same basic design, operating and physical principles, and construction methods and materials of the predicate magnets. The field strength of this magnet is 6000 gauss (0.6T). This magnet configuration is essentially a combination of basic structural elements of Fonar's previously approved magnets. The two pole assemblies of the vertical-field iron-core electromagnet are separated and supported by steel supports that form the "walls", "ceiling" and "floor" of the room-sized magnet. This provides an unimpeded 360° access to the magnet's imaging gap. The electromagnet coil elements are windings of multiple turns of epoxy-insulated copper installed around the poles of the magnet frame, connected to a regulated power source, and chilled via the closed loop chiller system.

During operation, the poles of the magnet establish a vertical magnet field with a limited fringe field. The magnetic field is created by passing a regulated DC current through the coil windings surrounding the magnet poles. The field strength is proportional to the amount of current in the coils. In this magnet the current supplied will result in a magnetic field of 6000 gauss, ± 5% (0.6T ± 5%), operating at frequencies between 24.27 and 26.92 MHz. This magnet functions with all imaging sequences available in the current software releases. All other non-magnet related equipment and procedures used are as previously reviewed by the FDA in PMA 830076, its supplements, and the 510(k) submissions K910839 and K951681.

FONAR 360° and Predicate Magnet Comparisons

The table below compares and summarizes the common specifications for the predicate devices and the FONAR 360° magnet. The table shows that the FONAR 360° specifications compare favorably with those of Fonar's previously approved magnets.

MAGNET CONFIGURATIONS			
Magnet Specification	B3000 Permanent Magnet	QUAD 12000 Electromagnet	FONAR 360° Electromagnet
Type	Permanent Magnet	Iron-core Electromagnet	Iron-core Electromagnet
Field Strength	0.3 T ± 10%	0.6 T ± 5%	0.6 T ± 5%
Calculated SAR	.19 W/kg	0.76 W/kg	0.76 W/kg
Power Consumption	N/A	98 kVA	98 kVA
Magnet Coil Winding Material (Each Pole)	N/A	Copper Bar with hollow core cooling	Copper Bar with hollow core cooling
Cooling	N/A	30 ton closed loop liquid chiller	30 ton closed loop liquid chiller
Stability (magnet drift)	long-term < 2 ppm/hr short term < .3 ppm/min	long-term < 2 ppm/hr short term < .3 ppm/min	long-term < 2 ppm/hr short term < .3 ppm/min
Field Homogeneity	3 ppm within 30 cm DSV 1 ppm within 20 cm DSV	3 ppm within 30 cm DSV 1 ppm within 20 cm DSV	3 ppm within 30 cm DSV 1 ppm within 20 cm DSV
Shimming	passive and active 16 shim coil pairs	passive and active 16 shim coil pairs	passive and/or active 16 shim coil pairs
Open Gap™ Configuration	13" vertical clearance 26.25" horiz. aperture	19" vertical clearance 49" horiz. aperture	19" vertical clearance 14' horizontal axis
Fringe Field (5 Gauss Line – from magnet center)	8.0 ft toward bed 7.0 ft toward rear 6.5 ft either side	13 ft toward bed 9 ft toward rear 7.5 ft either side	9 ft vertically 10 ft toward front or rear 8.75 ft to either side
Pole Cap Eddy Current Compensation	Steel pole with inlaid laminates	steel pole with inlaid laminates or self-shield gradients	steel pole with inlaid laminates or self-shield gradients
Outer Dimensions (h x l x w)	110" x 110" x 197	90" x 124" x 124"	132" x 120" x 192"
Weight (w/ base)	220,000 lbs. (Approx.)	100,000 lbs. (Approx.)	350,000 lbs. (Approx.)

The Fonar 360° Transmitter Coil

The transmitter coil for the Fonar 360° is modified from the coil used in the Quad 12000 magnet to accommodate the openness of the gap and the removal of the vertical posts of the Quad magnet construction. The resulting transmitter coil is configured as a quadrature coil instead of the linear coil used in the Quad. While the construction methods are different, the resulting field after application of the RF power produces the same level of excitation as the previously approved coils, and results in images that are equivalent to those produced by the predicate devices

Decoupling Circuits

To prevent the elements of the transmitter coil from directly interacting with the coil elements of the receiver coil it is necessary to isolate them from each other "electrically". This is accomplished through the use of a decoupling circuit that prevents the signal from the transmitter coil from being picked up by the receiver coils. This can easily be accomplished with common circuits and components. Basically, resonant circuits are tuned to the correct frequencies, and silicon rectifiers are used as switching elements to control the impedance of the receiver coil circuit to prevent the receiver coil from "seeing" the transmitted waveform.

Indications for Use

The FONAR 360° Magnetic Resonance Imaging System is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast upon NMR parameters [hydrogen nuclei concentration and flow velocity, T1 (spin-lattice relaxation time) and T2 (spin-spin relaxation time)]. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

WARNING: This device is limited by U.S. Federal law to investigational use for indications not in the indications statement.

Under the requirements of the law, the non-indicated applications can be used only under an Institutional Review Board approved protocol for a non-significant risk device or an Investigational Device Exemption application approved by the FDA for a significant risk device. The procedures to be followed, under the sponsorship of FONAR Corporation, are determined by the current guidelines established by the FDA, which should provide the IRB with sufficient guidance to determine the level of risk for a MRI device.

WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

Description of Safety and Substantial Equivalence

MRI effectiveness parameters such as spatial resolution, geometric distortion, specification volume, image uniformity, and slice spacing are essentially unchanged by the new magnet. A series of non-clinical tests and a period of human imaging were performed to demonstrate the safety and effectiveness of the FONAR 360° magnet, and to establish substantial equivalence to the predicate magnets. All testing was conducted in accordance with current FDA guidance documents and applicable device regulations, such as the NEMA standards. Results from all testing demonstrate substantial equivalence to the predicate devices.

Non-Clinical Testing

The following specific parameters have been identified by the FDA as being pertinent to patient safety and highlighted for inclusion in 510(k) submissions. The majority of these concerns are specifically tested by comparison to the NEMA standards. The results of those NEMA tests not listed below will be included in this summary in tabular form. The new magnet does not significantly affect any of these parameters. The FONAR 360° magnet values for each of the concerns are indicated below.

a. Static Field Strength: 0.6T ± 5%
b. Peak A-Weighted acoustic noise: 88.2 ± 0.8 dBA
c. Description of operational modes of the system: Normal mode only
d. Maximum SAR for transmitter: <0.1 W/kg measured (NEMA)– 0.76 W/kg calculated
e. Maximum dB/dt (pulsing X, Y and Z gradients): 16.53 T/s ± 0.31
f. Potential emergency conditions and means for shutdown: Switch on console
g. Biocompatibility of materials: No new materials or invasive uses

The testing for characteristics not listed above include:

a. Signal-to-Noise (SNR): Body – 41 ± 3.5% Head – 104 ± 3.1%
b. Geometric Distortion: Body – o.53% to 3.94% Head – 0.49% to 1.78%
c. Image Uniformity: Body Average - ± 46.67% Head Average - ± 26.3%
d. Slice Thickness: se20 Avg. Error ± 0.21 mm - se30 Avg. Error ± 0.22 mm
e. Spatial Resolution: Min. pixel dimension – 0.5 mm
Min. phantom resolution element – 0.46 mm

Clinical Testing

A period of human imaging was performed in accordance with current FDA guidance documents and applicable device regulations that demonstrate the clinical utility of the FONAR 360° magnet. The images provide verification that the FONAR 360° magnet is effective in producing high-quality images with good signal intensity and image uniformity. These clinical tests have provided sufficient experience to demonstrate the substantial equivalency of the FONAR 360° magnet to the previously approved scanners, with no serious malfunctions or adverse effects to patient health or safety reported.

Summary

The material presented within this submission has demonstrated that the FONAR 360° magnet is substantially equivalent to previously approved FONAR MRI magnets under their current conditions for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2000

Luciano Bonanni
Executive Vice President
FONAR Corporation
110 Marcus Drive
Melville, NY 11747-4292

Re: K994287
FONAR 360° Magnetic Resonance Imaging Scanner
Dated: December 9, 1999
Received: December 20, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Bonanni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

STATEMENT OF INDICATIONS FOR USE

Applicant: FONAR CORPORATION
510(k) Number (if known): K994287
Device Name: FONAR 360° Magnetic Resonance Imaging Scanner

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Daniel A. Steyer
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994287

Prescription Use ✓
(Per 21 CFR 801.109)